



1631 #6 10/12/510  
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**PATENT APPLICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GRASS et al.

Art Unit: 1631

Serial No.: 09/786,361

Filed: March 14, 2001

Attorney Docket No. 109904-00015

For: PHARMACOKINETIC-BASED DRUG DESIGN TOOL AND METHOD

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Washington, D.C. 20231  
Sir:

July 17, 2001

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the information item(s) listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each item(s) is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the item(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

1. This Information Disclosure Statement is being filed (a) within three months of the U.S. filing date, OR (b) before the mailing date of a first Office Action on the merits in the present application, OR (c) accompanies a Request for Continued Examination. No certification or fee is required.
2. The Examiner's attention is directed to co-pending U.S. Patent Application Nos. 09/786,362 filed March 14, 2001; 09/320,544 filed May 26, 1999, 09/320,545, filed May 26, 1999; 09/320,371, filed May 26, 1999; 09/320,069, filed May 26, 1999; 09/320,270 filed May 26, 1999; and 09/320,372 filed May 26, 1999, which are directed to related technical subject matter. The identification of these U.S. Patent Applications are not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination of the present application.

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3. In addition to the references already cited in this application, those cited in the applications identified above, and those cited in the associated PCT applications (international search reports, written opinions, and preliminary examination reports are included in this IDS), Applicants, due to the number of references cited, would like to point out that an article by one of the inventors, Grass, George, "Simulation models to predict oral drug absorption from in vitro data", Advanced Drug Delivery Reviews, (1997) Vol. 23, pp. 199-219, appears to be one of the more relevant references.

Respectfully submitted,



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**Section A**

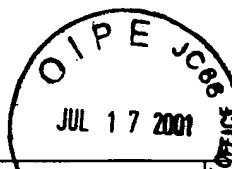
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**Section B**

<u>APPLICATION SERIAL NUMBER</u>	<u>FILING DATE</u>	<u>STATUS</u>
09/320,069	26 May 1999	Pending
09/320,270	26 May 1999	Pending
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09/320,372	26 May 1999	Pending
09/320,544	26 May 1999	Pending
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## LIST OF REFERENCES CITED BY APPLICANT

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AB	Audus et al., "The Use of Cultured Epitheelial and Endothelial Cells for Drug Transport and Metabolism Studies", <u>Pharmaceutical Research</u> (1990) Vol. 7, No. 5, pp 435-451
AC	Bailey et al., "The Use of the Intestinal Epithelial Cell Culture Model, Caco-2 in Pharmaceutical Development", <u>Advanced Drug Delivery Reviews</u> (1996) Vol. 22 pp. 85-103
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AL	Jezyk et al., "Permeability Characteristics of Various Intestinal Regions of Rabbit, Dog, and Monkey", <u>Pharmaceutical Research</u> (1992) Vol. 9, No. 12, pp. 1580-1586
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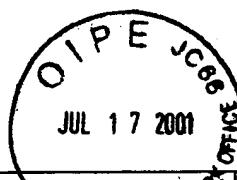
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BF	Berger et al., "Combining Statistical, Rule-Based, and Physiologic Model-Based Methods to Assist in the Management of Diabetes Mellitus", <u>Computers and Biomedical Research</u> (1990) Vol. 23, pp. 346-357
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BX	Gomeni et al., 'IGPHARM: Interactive Graphic Package for Pharmacokinetic Analysis', <u>Computers and Biomedical Research</u> (1978) Vol. 11, pp. 345-361

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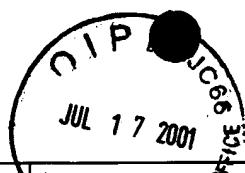
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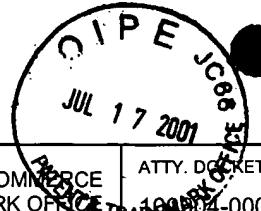
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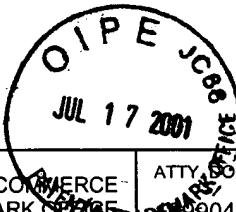
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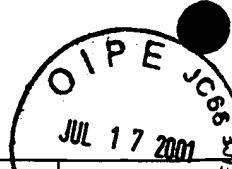
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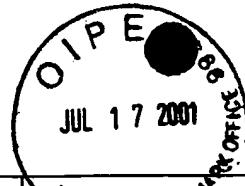
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	FC	4,411,989	10/25/83	Grow	435	20	08/13/81
	FD	4,775,794	10/04/88	Behmann	250	373	11/02/87
	FE	4,952,061	08/28/90	Edgar	356	407	06/27/88
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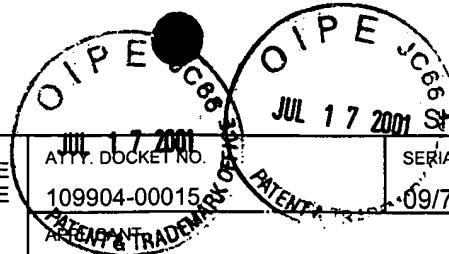
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	FI	WO 94/23705	10/27/94	PCT	A61K	9/48	
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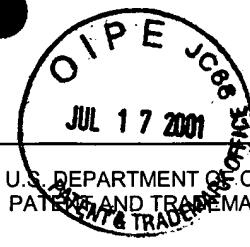
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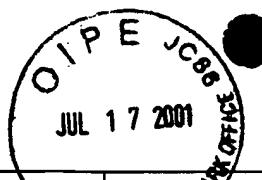
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